

CLAIMS

What is claimed is:

- 5 1. An HIV DNA vaccine composition comprising
 a nucleic acid expression vector comprising at least one HIV Gag- or Env-
 encoding sequence; and
 PLG.
- 10 2. The vaccine composition of claim 1, wherein the concentration of PLG is
 between about 5 and 100 fold greater than the concentration of the nucleic acid expression
 vector.
- 15 3. The vaccine composition of claim 2, wherein the concentration of nucleic acid
 is between about 10 µg/mL and 5 mg/mL and the concentration of the PLG is between
 about 100 µg/mL and 100 mg/mL.
- 20 4. The vaccine composition of claim 1, wherein the nucleic acid concentration per
 dose is between approximately 1 µg/dose and 5 mg/dose and the PLG concentration per
 dose is between approximately 10 µg/dose and 100 mg/dose.
- 25 5. The vaccine composition of any of claims 1 to 4, as set forth in Table 1 or Table
 2.
- 30 6. The vaccine composition of any of claims 1 to 4, as set forth in column 2 of
 Table 9.
- 35 7. An HIV vaccine composition comprising
 oligomeric gp140 (o-gp140); and
 a pharmaceutically acceptable excipient.
- 40 8. The HIV vaccine of claim 7, wherein the concentration of o-gp140 is between
 about .1 and 10 mg/mL.
- 45 9. The HIV vaccine of claim 7, wherein the concentration of o-gp140 per dose is
 approximately 100 µg/dose.
- 50 10. The HIV vaccine of claim 7, as set forth in Table 3 or Table 11.

11. The HIV vaccine of claim 7, further comprising an adjuvant.
12. The HIV vaccine of claim 11, wherein the adjuvant is MF59 or CpG.
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13. The HIV vaccine of claim 12, wherein the adjuvant is MF59 and MF59 is as set forth in Table 4.
14. An HIV vaccine comprising an HIV Env DNA vaccine according to any one of claims 1-6; an HIV Gag DNA vaccine according to any one of claims 1-6; and an HIV vaccine according to any one of claims 7-13.
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15. A method of generating an immune response in a subject, comprising (a) administering at least one HIV vaccine composition according to any of claims 1-14 to the subject, and
15 (b) administering, at a time subsequent to the administering of step (a), at least one HIV vaccine composition according to any of claims 1 to 14.
16. The method of claim 15, wherein step (a) comprises administering at least one vaccine composition according to any of claims 1-6 and step (b) comprises administering at least one vaccine composition according to any of claims 7-13.
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17. The method of claim 16, wherein step (a) comprises multiple administrations of at least one vaccine composition according to claims 1-6 and step (b) comprises multiple administrations of at least one vaccine composition according to any of claims 7-13.
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18. The method of claim 17, wherein step (a) comprises two or three administrations at one month intervals; step (b) comprises two or three administrations at 1, 2 or 3 month intervals; and the time between the administrations of step (a) and step (b) is 1 to 5 months.
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19. The method of any of claims 15 to 18, wherein step (a) comprises administering at least one HIV Gag vaccine and at least one HIV Env vaccine.
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20. The method of claim 15 or claim 18, wherein step (b) comprises concurrently administering at least one DNA vaccine according to any of claims 1-6 and at least one HIV vaccine according to any of claims 7-13.

21. The method of any of claim 20, wherein step (a) comprises administering at least one HIV Gag vaccine and at least one HIV Env vaccine.

5 22. The method of any of claims 15-21, wherein at least one administration is intramuscular or intradermal.

10 23. A method of making oligomeric HIV Env gp140 proteins, comprising the steps of introducing a nucleic acid encoding gp140 into a host cell; culturing the host cell under conditions such that gp140 is expressed in the cell; and isolating oligomeric gp140 (o-gp140) protein from the host cell.

15 24. The method of claim 23, wherein the o-gp140 is secreted from the cell and isolated from the cell supernatant.

20 25. A method of making an HIV DNA vaccine according to any of claims 1-6, comprising the step of combining a nucleic acid expression vector comprising a sequence encoding one or more HIV polypeptides with aseptic PLG microparticles such that the nucleic acid binds to the PLG microparticles to form a DNA/PLG HIV vaccine.

25 26. The method of claim 25, further comprising the step of lyophilizing the DNA/PLG HIV vaccines.

27. A method of making an HIV vaccine according to any of claims 7-13, comprising combining o-gp140 with an adjuvant.